NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK & CO., INC. and MERCK SHARP & DOHME CORP.., Plaintiffs, v. SANDOZ INC., Defendant.	Civil Action No. 10-1625 (SRC) (PS) Civil Action No. 10-2308 (SRC) (PS) **OPINION**

CHESLER, U.S.D.J.

This matter comes before the Court on the applications by Plaintiffs Merck & Co., Inc. and Merck Sharp & Dohme Corp. (collectively, "Merck") and Defendant Sandoz Inc. ("Sandoz") for claim construction to resolve disputes over the construction of claim terms in U.S. Patent Nos. 5,378,804 (filed Mar. 16, 1993) (the "'804 patent") and 5,952,300 (filed Mar. 28, 1997) (the "'300 patent").

BACKGROUND

This matter involves two Hatch-Waxman actions for patent infringement. The cases have been consolidated for pretrial purposes and arise from the following facts. Briefly, Merck owns the '804 and '300 patents, which are directed to compounds and compositions associated with Merck's antifungal drug Cancidas®. Defendant is a generic pharmaceutical manufacturer who has filed an Abbreviated New Drug Application seeking FDA approval to engage in the manufacture and sale of generic versions of Cancidas® prior to the expiration of the Merck patents.

When the parties originally briefed this matter, briefs were filed by Defendant Teva Parenteral Medicines, Inc. ("Teva.") The action between Merck and Teva has since been settled.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). The Court decides claim construction as a matter of law: "the construction of a patent, including terms of art within its claim, is exclusively within the province of the court." Markman v. Westview Instruments, 517 U.S. 370, 372 (1996).

The focus of claim construction is the claim language itself:

> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.
> The inquiry into how a person of ordinary skill in the art understands a claim term

> provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed term in the '804 patent

The parties dispute the meaning of claim 2 of the '804 patent, which states: "A compound having the formula:" and then gives a diagram of a molecule. The parties dispute – if obliquely – whether this claim includes the pharmaceutically acceptable salts of the compound depicted.

Merck proposes this construction: "A compound having the structure depicted in claim 2." (Pl.'s Br. 7.) There is no dispute that claim 2 is limited to compounds having the structure depicted – this merely states the obvious. The real disputed issue, however, is whether this structure includes or excludes the pharmaceutically acceptable salts of the compound depicted. Yet all that Merck's brief says on this subject is that Sandoz' position seeks to add a negative limitation to the claim (the exclusion of salt forms). This is also true – and Merck does not present any persuasive argument as to why Sandoz' proposed construction is wrong.

Merck's opening brief simply lacks any argument which explains how one gets from its

proposed construction to the conclusion that Sandoz is wrong, and that salt forms are included.[1] One might have expected Merck to support its position with a statement from an expert that the skilled artisan, looking at that chemical diagram, would understand it to cover salt forms. This is not, however, the case. Although Merck points to the declaration of its expert, Dr. Byrn, that declaration states: "The chemical structure in claim 2 describes the molecule caspofungin." (Byrn Dec. ¶ 27.) Absent some further explanation, this would appear to support the position of Sandoz. Conspicuously absent is any statement from Dr. Byrn to the effect that the skilled artisan would understand a diagram of the molecule caspofungin to refer also to its salts. Dr. Byrn's declaration does not help Merck bridge the gap between the diagram of caspofungin and coverage of caspofungin salts.

Sandoz, on the other hand, makes a number of claim construction arguments. First, it notes three other Merck patents in which the claims contain language that expressly includes pharmaceutically acceptable salts of the compound. Sandoz argues that this shows that Merck knew how to draft claims to include salts, and it chose not to do so in the '804 patent. This makes sense, but the problem is that this is claim construction through extrinsic evidence, whereas, under Federal Circuit precedent, intrinsic evidence carries much greater weight.

Far more persuasive is Sandoz' argument based on the prosecution history. Sandoz points to the following in that history. The applicant had originally submitted claims which

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[1] Merck's argument really appears to assert that, even if the claim does not specifically cover acid salt forms, Defendant would nevertheless necessarily infringe the claims of the patent by manufacturing an acid salt form. Merck argues that by so doing, Defendant uses or induces others to use caspofungin base. This legal theory can and will be tested during motion practice devoted to resolving the substantive issue of infringement. It does not bear on the issue of whether the claim language, by its terms, can properly be understood by the skilled artisan as covering acid salt forms of the diagramed compound.

included the acid addition salts of caspofungin.[2] In the office action dated August 19, 1993, the examiner rejected, *inter alia*, three claims:

> Claims 1, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.
>
> A). The metes and bounds of the claimed acid addition salts is indefinite since the spec. merely provides examples of said salt but appears not to limit said salt to those recited. (E.g., claim 1.)

(Lemek Dec. Ex. 6 at 4.) In the office action dated February 10, 1994, the examiner again rejected these three claims, citing the explanation quoted above, and adding:

> A). Contrary to applicants' assertion a person a [sic] skilled in the art would not be appraised of the scope of the claimed "acid addition salts". Does said salt refer to organic, inorganic, combination of both, a simple or complex salt? As stated in the last Office action the spec. merely provides some examples of said salt but appears not to limit them to those recited therein.

(Lemek Dec. Ex. 8 at 7-8.) The applicant subsequently withdrew all rejected claims, and the patent issued.

Sandoz contends that, when the applicant withdrew the claims to overcome the examiner's rejection of them, the applicant surrendered coverage of the salts that it now seeks to include. This has merit and, significantly, Merck's briefs do not address the prosecution history at all.

"The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Southwall Technologies v. Cardinal IG

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[2] Of the 14 originally submitted claims, claim 1 claimed a compound of a specified formula "and acid addition salts thereof." (Lemek Dec. Ex. 5 at 67.) Claims 2 through 13 depended on claim 1. Claim 14 neither depended on claim 1 nor included any language about salts.

Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995). It does appear that, during prosecution, the applicant surrendered coverage of acid addition salts in order to obtain patentability, and that Merck "cannot now submit an interpretation of the claims to cover what was disclaimed." Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1327 (Fed. Cir. 2002). Having disclaimed coverage of acid addition salts, Merck may not now argue for an interpretation that has the effect of undoing the examiner's rejection.

Sandoz also argues that the specification distinguishes between the claimed compound and its salts, which is true, but not of much significance. No one contends that the claimed compounds are interchangeable with their salts. This observation about the specification, however, leads the Court to observe that the specification expressly includes the salts within the scope of the invention. The specification begins with this statement: "The present invention is directed to certain aza cyclohexapeptide compounds and to processes for their preparation." '804 Patent col.1 ll.4-6. The specification then gives a technical description of these compounds which ends with this phrase: "and acid addition salts thereof." Id. col.1 ll.51-52. Later, the specification states: "The invention also embraces acid addition salts." Id. col.11 ll.47. The claims, however, contain no language that expressly includes acid addition salts. There thus appears to be some incongruity between the specification and the claims.

This issue has not been raised by the parties, and Merck does not rely on the specification language which includes salts to support its claim construction position. Nor does this Court believe that the incongruity presents a substantial problem for the claim construction, even though, as a consequence, it appears that Sandoz urges the Court to adopt a claim construction

that excludes some preferred embodiments disclosed in the specification.[3] The Federal Circuit has stated:

> Although we recognize that an interpretation excluding a preferred embodiment is rarely, if ever, correct and would require highly persuasive evidentiary support, where the prosecution history requires a claim construction that excludes some but not all of the preferred embodiments, such a construction is permissible and meets the standard of highly persuasive evidentiary support.

Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1327 (Fed. Cir. 2002) (quotations omitted). Such is the case here. Because Sandoz has persuaded this Court that the prosecution history requires a claim construction that excludes some, but not all, of the preferred embodiments, this constitutes the highly persuasive evidentiary support required to adopt an interpretation which excludes a preferred embodiment.[4]

This Court concludes that, because the applicant disclaimed coverage of acid addition salts during prosecution, claim 2 excludes the pharmaceutically acceptable salts of the compound depicted.

III. Claim construction of the disputed terms in the '300 patent

The parties dispute the meaning of claim 1 of the '300 patent. This claim contains a chemical diagram and states:

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[3] As Sandoz contends, Merck's expert conceded this at deposition, when he stated that claim 2 did not cover the molecule depicted in Example 2 of the specification. (Lemek Supp. Dec. Ex. A 107:9-108:8.) Furthermore, this would appear to strongly undercut Merck's claim construction position, since its own expert said that the diagram in Claim 2 did not cover the caspofungin salt depicted in Example 2.

[4] The Court observes that it appears that, when the applicant submitted the original application, the patent was drafted so as to include coverage of acid addition salts. After the examiner twice rejected the claims covering acid addition salts, those claims were withdrawn, but the specification was not rewritten to reflect that change.

> 1. A pharmaceutical composition for intravenous administration to a patient comprising
> a) a pharmaceutically effective amount of a compound having the formula [diagram] and the pharmaceutically acceptable salts thereof,
> b) a pharmaceutically acceptable amount of an excipient effective to form a lyophilized cake; and
> c) a pharmaceutically acceptable amount of an acetate buffer effective to provide a pharmaceutically acceptable pH.

The parties dispute the meaning of the phrase "and the pharmaceutically acceptable salts thereof." Merck contends that this phrase, in the context of subphrase "a)," means that the composition comprises either an amount of the diagramed compound or an amount of a pharmaceutically acceptable salt of the diagramed compound. Sandoz contends that this phrase, in the context of subphrase "a)," means that the composition comprises an amount which contains both the diagramed compound and its pharmaceutically acceptable salts.

Sandoz proposes a claim construction that is problematic for several reasons. First, it renders the phrase at issue indefinite, as it is then unclear whether the composition includes all the pharmaceutically acceptable salts thereof, or just two or more (since "salts" is plural). If it is not all the salts, which salts are chosen? As Merck notes, even Teva's expert, Dr. Grieco, stated that he did not read the patent to call for adding in every possible salt form. (Leonard Supp. Dec. Ex. L 129:14-19.) Merck's expert, Dr. Byrn, stated that the specification describes a general process for preparing the claimed compositions which involves using the caspofungin base and no salt forms. (Byrn Dec. ¶ 37.) The interpretation advocated by Sandoz is not consistent with the general manufacturing process stated in the specification.

Second, the construction proposed by Sandoz is not consistent with the surrounding claim language. Subphrase "a)" refers to an "amount of **a** compound." The ordinary meaning of "a"

compound is "a single" compound. Sandoz proposes, however, that subphrase "a)" requires an amount of more than one compound – it requires an amount of caspofungin base, and an amount of a caspofungin salt. Sandoz has presented nothing to support the proposition that this combination of at least two compounds is consistent with the claim language requiring a single compound.

Third, an analysis of how claim 1 is structured supports Merck's position. One of the most salient features of claim 1 is its use of subphrases, which are signaled by the use of a lower case letter and a parenthesis, set off in a separate line. The subphrases are conjunctive: there are three of them, and it is clear that the element described by each subphrase is required. Thus, within claim 1, the patentee chose a way to express mandatory conjunction. The patentee did not, however, draft a separate subphrase referring to the pharmaceutically acceptable salts of the diagramed compound. This indicates that the patentee did not intend for the "and" preceding "pharmaceutically acceptable salts thereof" to express mandatory conjunction.

Fourth, as Merck contends, the specification expressly treats the base and its salts as alternative active ingredients:

> The dosage regimen utilizing the compositions of the present invention is selected in accordance with a variety of factors including type, species, age, . . . and the particular active ingredient ***or*** salt thereof employed.

'300 Patent col.4 ll.22-29 (emphasis added). This clearly treats the base and its salts as alternative active ingredients and supports Merck's proposed construction. Also, in Example 1 of the specification, only the diacetate salt of caspofungin is used in the composition. (Byrn Dec. ¶ 39.) Example 1 does not call for the use of both caspofungin base and its salt. The specification is consistent with Merck's construction, and not that of Sandoz.

Lastly, the Federal Circuit has instructed that, in construing claims, courts should consider what the inventor actually invented:

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

Phillips, 415 F.3d at 1316 (quoting Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998)). Here, there is no evidence – nor has Sandoz even argued this – that what the inventor actually invented was a product that is a combination of caspofungin base and some or all of its salts. Thus, the construction proposed by Sandoz does not naturally align with the patent's description of the invention.

This Court concludes that subphrase "a" in Claim 1 of the '300 patent should be construed to require either an amount of the diagramed compound or an amount of a pharmaceutically acceptable salt of the diagramed compound.

CONCLUSION

This Court has examined the disputes over claim construction raised by the parties. As to claim 2 of the '804 patent, the Court concludes that claim 2 excludes the pharmaceutically acceptable salts of the compound depicted. As to claim 1 of the '300 patent, the Court concludes that subphrase "a" in Claim 1 of the '300 patent should be construed to require either an amount of the diagramed compound or an amount of a pharmaceutically acceptable salt of the diagramed compound. .

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: March 3, 2011